

REMARKS**I. APPLICANTS' INVENTION**

The present invention relates to an implantable electrode provided with a thin, porous, wettable polymeric covering. The electrode covering of the present invention tightly conforms to the external profile of an electrode, which minimizes air gaps and voids. The electrode covering is relatively thin, preferably less than 0.13 mm thick, and is treated to enhance rapid wetting by bodily fluids. The combination of minimal air gaps, tight conformance to the electrode, wettability and porosity of the thin covering, allows repeated, high energy electrical discharges to be transmitted without significant bubble formation, sparking or degradation of the covering. In addition, the electrode covering of the present invention has pore sizes tailored to minimize cellular ingrowth and tissue attachment thereby allowing a less traumatic removal of the electrode after implantation if extraction becomes necessary, for example due to infection or electrode dislodgment.

II. CLAIM REJECTIONS

All claims stand rejected over US Patent Application Publication No. 2002/014786 to Soukup et al. Specifically, claims 1-6, 8-12, 15-21, 42-47, 50 and 51 are rejected under 35 U.S.C. 102(e) as anticipated by this reference. Claim 7 is rejected as unpatentable over Soukup et al. under 35 U.S.C. 103(a). Claims 13, 14, 22-41, 48 and 49 are rejected under 35 U.S.C. 103(a) as unpatentable over Soukup et al. in view of Carson, US 5,931,862.

Applicants submitted a declaration under 37 CFR 1.131 with their previous paper. The declaration was signed by Robert C. Krall, one of the inventors of the present application, and stated generally that the applicants were in possession of the claimed invention, particularly with regard to relevant claim elements relating to the Soukup et al. reference, prior to the filing date of that reference. In particular, the declaration stated that the covered electrode of the present invention had a porous polymeric covering of about 0.23mm thickness, clearly less than the maximum thickness limitation of 0.13mm required by the claims. Several exhibits were attached to the declaration including a copy of a relevant page from the lab notebook of Mr. Krall describing the manufacture of a batch of electrodes sent to another organization for animal testing. Copies of two photographs of a retained sample electrode (no. 7109104572) from this batch were also attached.

The Examiner states that the declaration is considered ineffective, adding that "No evidence has been submitted to show that the applicants had in their possession prior to the date of the Soukup et al. reference, an implantable defibrillator electrode lead with an electrode cover having a thickness of less than about 0.13mm."

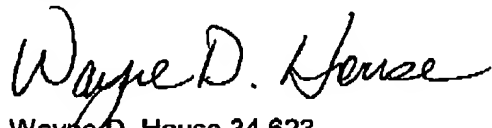
Applicants are of the position that the declaration of the inventor constitutes a statement of fact, and should be sufficient to confirm the thinness of the electrode covering. Regardless, a second declaration is presented at this time that describes an independent measurement of the thickness of the covering of retained electrode sample no. 7109104572. The statement is presented by a person well-qualified to perform the thickness measurement and employed by the present assignee.

As further stated in this second declaration, the thickness of the porous polymer covering of this retained sample electrode is clearly less than the thinness required by the claim and antedates the Soukup et al. reference. Accordingly, all three rejections are now moot.

CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully Submitted,



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